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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,202	06/29/2006	Simon Michael West	05-221-US	4070
718	7590	09/27/2006	EXAMINER	
REED SMITH LLP			SHIAO, REI TSANG	
P.O. BOX 488				
PITTSBURGH, PA 15230-0488			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,202	<b>Applicant(s)</b> WEST ET AL.	
	<b>Examiner</b> Rebecca L. Anderson	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.                                                |

### DETAILED ACTION

Claims 21 are currently pending in the instant application and are subject to a lack of unity requirement.

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to the numerous and widely divergent subject matter claimed, a precise listing of inventive groups cannot be made. The following groups are exemplary:

**Group I**, Claims 1, 2 and 14-16 and 20 (in part) drawn to a phosphatide of pravastatin and derivatives thereof.

**Group II**, Claims 1, 2 and 14-16 and 20 (in part) drawn to a phosphatide of atorvastatin and derivatives thereof.

**Group III**, Claims 1, 2 and 14-16 and 20 (in part) drawn to a phosphatide of venlafaxine and derivatives thereof.

**Group IV**, Claims 5-7 (in part) drawn to a method for phosphorylating pravastatin.

**Group V**, Claims 1-2 (in part) drawn to phosphate derivatives other than those found in Groups I, VI-X and XXXV with pravastatin and derivatives thereof.

**Group VI**, Claims 1, 3 and 4 (in part) drawn to a phosphate derivative which is a complex, the complexing agent being amphoteric surfactants with pravastatin and derivatives thereof.

**Group VII**, Claims 1, 3 and 4 (in part) drawn to a phosphate derivative which is a complex, the complexing agent being cationic surfactants with pravastatin and derivatives thereof.

**Group VIII**, Claims 1, 3 and 4 (in part) drawn to a phosphate derivative which is a complex, the complexing agent being amino acids having nitrogen functional groups with pravastatin and derivatives thereof.

Art Unit: 1626

**Group IX**, Claims 1, 3 and 4 (in part) drawn to a phosphate derivative which is a complex, the complexing agent being proteins rich in amino acids having nitrogen functional groups with pravastatin and derivatives thereof.

**Group X**, Claims 1-2 (in part) drawn to phosphate derivatives other than those found in Groups II, XI-XIV and XXXVI with atorvastatin and derivatives thereof.

**Group XI**, Claims 1, 3 and 4 (in part) drawn to a phosphate derivative which is a complex, the complexing agent being amphoteric surfactants with atorvastatin and derivatives thereof.

**Group XII**, Claims 1, 3 and 4 (in part) drawn to a phosphate derivative which is a complex, the complexing agent being cationic surfactants with atorvastatin and derivatives thereof.

**Group XIII**, Claims 1, 3 and 4 (in part) drawn to a phosphate derivative which is a complex, the complexing agent being amino acids having nitrogen functional groups with atorvastatin and derivatives thereof.

**Group XIV**, Claims 1, 3 and 4 (in part) drawn to a phosphate derivative which is a complex, the complexing agent being proteins rich in amino acids having nitrogen functional groups with atorvastatin and derivatives thereof.

**Group XV**, Claims 1-2 (in part) drawn to phosphate derivatives other than those found in Groups III, XVI-XIX and XXXVII with venlafaxine and derivatives thereof.

**Group XVI**, Claims 1, 3 and 4 (in part) drawn to a phosphate derivative which is a complex, the complexing agent being amphoteric surfactants with venlafaxine and derivatives thereof.

**Group XVII**, Claims 1, 3 and 4 (in part) drawn to a phosphate derivative which is a complex, the complexing agent being cationic surfactants with venlafaxine and derivatives thereof.

**Group XVIII**, Claims 1, 3 and 4 (in part) drawn to a phosphate derivative which is a complex, the complexing agent being amino acids having nitrogen functional groups with venlafaxine and derivatives thereof.

**Group XIX**, Claims 1, 3 and 4 (in part) drawn to a phosphate derivative which is a complex, the complexing agent being proteins rich in amino acids having nitrogen functional groups with venlafaxine and derivatives thereof.

Art Unit: 1626

Group XX, Claims 5-7 (in part) drawn to a method of phosphorylating atorvastatin.

Group XXI, Claims 5-7 (in part) drawn to a method of phosphorylating venlafaxine.

Group XXII, Claims 5 and 7 (in part) drawn to a method of phosphorylating secondary hydroxyl compounds other than pravastatin, atorvastatin and venlafaxine.

Group XXIII, Claim 8 (in part) drawn to an additional method of phosphorylating pravastatin with the additional step b).

Group XXIV, Claim 8 (in part) drawn to an additional method of phosphorylating atorvastatin with the additional step b).

Group XXV, Claim 8 (in part) drawn to an additional method of phosphorylating venlafaxine with the additional step b).

Group XXVI, Claim 8 (in part) drawn to an additional method of phosphorylating secondary hydroxyl compounds other than pravastatin, atorvastatin and venlafaxine with the additional step b).

Group XXVII, Claims 9 and 11 (in part) drawn to an additional method of phosphorylating pravastatin with the additional step b').

Group XXVIII, Claims 9 and 11 (in part) drawn to an additional method of phosphorylating atorvastatin with the additional step b').

Group XXIX, Claims 9 and 11 (in part) drawn to an additional method of phosphorylating venlafaxine with the additional step b').

Group XXX, Claims 9 and 11 (in part) drawn to an additional method of phosphorylating secondary hydroxyl compounds other than pravastatin, atorvastatin and venlafaxine with the additional step b').

Group XXXI, Claims 10 and 17 (in part) drawn to an additional method of phosphorylating pravastatin with the additional step c).

Group XXXII, Claims 10 and 17 (in part) drawn to an additional method of phosphorylating atorvastatin with the additional step c).

Group XXXIII, Claims 10 and 17 (in part) drawn to an additional method of phosphorylating venlafaxine with the additional step c).

Art Unit: 1626

Group XXXIV, Claims 10 and 17 (in part) drawn to an additional method of phosphorylating secondary hydroxyl compounds other than pravastatin, atorvastatin and venlafaxine with the additional step c).

Group XXXV, Claims 12, 13, 18, 19 and 21 (in part) drawn to a phosphate derivative of pravastatin and derivatives thereof reacted with P4O10 in the presence of an alkali metal salt of a fatty acid.

Group XXXVI, Claims 12, 13, 18, 19 and 21 (in part) drawn to a phosphate derivative of atorvastatin and derivatives thereof reacted with P4O10 in the presence of an alkali metal salt of a fatty acid.

Group XXXVII, Claims 12, 13, 18, 19 and 21 (in part) drawn to a phosphate derivative of venlafaxine and derivatives thereof reacted with P4O10 in the presence of an alkali metal salt of a fatty acid.

Group XXXVIII, Claims 12, 13, 18, 19 and 21 (in part) drawn to a phosphate derivative of secondary hydroxyl group compounds other than pravastatin, atorvastatin and venlafaxine and derivatives thereof reacted with P4O10 in the presence of an alkali metal salt of a fatty acid.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Again, this list is not exhaustive as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention (a product or a process of preparation) by identifying another specific embodiment of similar scope not listed in the exemplary groups of the invention and examiner will endeavor to group the same. The applicant may also choose to elect a single disclosed species or a single disclosed species for a single method of preparation and the examiner will endeavor to create a group comprising the elected species.

The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since, under 37 CFR 1.475(a)

Art Unit: 1626

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Groups I-XXXVIII lack unity of invention since under 37 CFR 1.475: the technical feature corresponding to the claims is a phosphate derivative of a compound having a secondary hydroxyl group. This technical feature is not a special technical feature because it fails to define a contribution over the prior art as can be seen, for example, by WO 02/40034, which discloses phosphate derivatives of hydroxylated active compounds such as those found on pages 9 and 10 which includes secondary hydroxyl containing compounds. Therefore claims 1-21 are not so linked as to form a single general inventive concept and there is a lack of unity of invention because they lack a special technical feature as the technical feature present fails to define a contribution over the prior art. The variables found in a phosphate derivative of a secondary hydroxyl group vary extensively and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter imposes a serious burden on any examination of the claimed subject matter.

Therefore, since the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical feature, the claims lack unity of invention and should be limited to only a product or a method of use.

Art Unit: 1626

Furthermore, in regards to groups I-XXXVIII even if unity of invention under 37 CFR 1.475(a) is not considered lacking, which it is, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and a process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

And, according to 37 CFR 1.475(c)

if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

Therefore, since the claims are drawn to more than a product and a method of use, and according to 37 CFR 1.475 (e)

the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

The claims, therefore, lack unity of invention.

### **Conclusion**

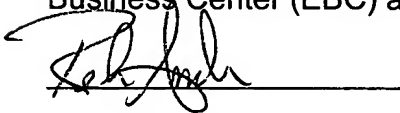
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Rebecca Anderson', is written over a horizontal line.

September 21, 2006

Rebecca Anderson  
Patent Examiner  
Art Unit 1626, Group 1620  
Technology Center 1600